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Section (viii)
Environmental Assessment

(Format following 21 CFR 25.31a, April 26, 1985)

The applicant is required to submit either a claim for categorical exclusion under 21 CFR 25.24 or an environmental assessment under 21 CFR 25.31.

(1) Date: November 30, 2004
(2) Name of applicant/petitioner: Stepan Company
(3) Address: 22 West Frontage Road, Northfield, IL 60093
(4) Description of Proposed Action:

The petitioner is requesting GRAS affirmation for Captrin.

Preparation of an environmental assessment is required for issuance of an affirmation of a GRAS substance pursuant to 21 CFR 25.22(a)(12). The petitioner plans to product Captrin at existing manufacturing facilities owned and operated by Stepan Company, located in Maywood, NJ. The manufacture of the substance is from commercial starting materials that are purchased.

Waste material generated in the manufacture of Captrin will be discharged or disposed of depending upon their characteristics.

1. No gases or vapors will be released to the atmosphere; part of the processing takes place under vacuum.
2. Liquid waste will be charged to a publicly owned treatment works.
3. Solid waste will be landfilled or incinerated.
4. ***Reaction byproducts (methanol, unreacted methyl esters) will be recovered and recycled into the process.***
5. Food grade that meet all pertinent regulations may be sold for animal feed. No hazardous wastes as defined by the Resources Conservation and Recovery Act (RCRA) will be generated in the manufacture of caprylic/capric triglycerides. The use of Captrin is to be as components of the human diet. The substance will be metabolized resulting from metabolism of other triglycerides. There will be no qualitative or quantitative change in the excretion of human waste. There also will be some waste in the production, preparation, and disposal of unused food products. This waste will be disposed of in the same manner as with other food waste.

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(1) Identification of the Chemical Substances that are Subject of the Proposed Action:

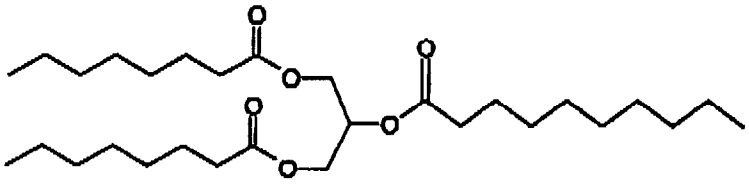
(a) Common or usual name: Captrin

(b) Chemical Name: ***Glycerides*** of linear saturated fatty acids primarily of chain lengths C_8 through C_{10}.

(c) Chemical Abstract Service (CAS) Registry Number: 73398-61-5

(d) Total Molecular Formulas:

(e) Structural Formula:



The fatty acids are randomly distributed on the glycerine backbone. The range of fatty acids is as follows:

n = 6 (caprylic acid) 3-95 weight percent
n = 8 (capric acid) 3-95 weight percent

Captrin consists of two medium chain fatty acids, C_8 or C_{10} on a glycerine backbone. The components of fatty acids are found in many dietary fats. Captrin is found in coconut and palm kern oils as well as milk and dairy products. Triglycerides that are high in capric acids are solid or paste at room temperature and those high in caprylic acid are liquid at room temperature.

Solubility of Captrin is similar to that of other triglycerides, i.e., it is insoluble in water and soluble in organic solvents. Captrin can be hydrolyzed to yield the components of fatty acids and glycerine.

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(1) Introduction of Substances into the Environment:

(a) For each site of production, list the substances expected to be emitted, state of controls exercised, and include a citation and statement of compliance with applicable emission requirements.

The production site of Captrin under the control of Stepan Company is at the Maywood, New Jersey facility of Stepan. The facility is in compliance with all applicable emission requirements and all occupational requirements.

(b) Controls exercised in certification of regulatory compliance during production.

Monthly testing and reporting to the Bergen County Utility Authority to show compliance to our Sanitary Sewer Permit.

The introduction will only take place at the Maywood, New Jersey facility of Stepan.

No specific regulations in regards to Captrin have been made as far as EPA NJDEPE or local authorities (Maywood or Bergen County Utility Authority) are concerned.

Exposure of employees to hazardous materials: NO OSHA, US EPA or NJDEPE hazardous materials are used in the production of Captrin.

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(1) Fate of Emitted Substances in the Environment:

(a) Air, cite lack of volatilization for air emissions at each site and in the ultimate disposition.

Emissions of Captrin and any of it breakdown products are not expected to enter the atmosphere during manufacture or normal use. The physical properties of the substances, i.e., low vapor pressure, high molecular weight, and high boiling point preclude the possibility of any significant air emissions. The materials used in the manufacture of Captrin are not expected to result in any air emissions.

(b) Fresh water, estuarine and marine ecosystems (water emissions).

The use of Captrin will not result in direct water emissions. The primary avenue of potential impact for the use of Captrin will be indirect through excretion of undigested parent compounds in the products of metabolism in human wastes. Since Captrin is digested at least as well as other common triglycerides in the diet, it is not expected that there will be an impact upon wastewater effluent discharges and/or sludge-amended soils. It is expected that the undigested triglycerides that do not enter water treatment processes will be further digested.

Fate of the waste in manufacture, discharged into municipal sanitary sewer. Oil and grease levels will be maintained at below 200 mg/l. Excess oil and grease removed by skimmers.

Fate of by products of manufacture, no production of byproducts of manufacture.

(c) Terrestrial ecosystems, no effect.

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(1) Effects of Released Substances:

Cite animal studies as it relates to lack of potential effects upon the environment. Captrin is composed of moieties that are of natural origin and are metabolized by animals using normal catabolic pathways.

(2) Use of Resources or Energy:

Identify starting materials.
Methyl caprylate, methyl caprate
Fatty Acids, caprylic and capric
Glycerin

There is no expected unusual demand for any natural resource or energy. There will be no effect upon endangered or threatened species nor property listed in or eligible for listing in the Federal Register of Historic Places.

(3) Mitigation Measures:

Describe any actions to mitigate potential adverse environmental effects. There are no adverse environmental effects that are inherent with the manufacture or use of the GRAS ingredient.

Additional measures which will be taken to avoid and/or mitigate releases to the environment include: spill protection around all liquid storage areas, the use of settling basins to capture settleable and floatable materials, secondary filters on the bag house dust control filters, and a strong corporate policy for the management of materials in an environmentally safe manner. Production operations will be under the supervision of qualified engineers and managers. Stepan will continue to provide training for personnel on emergency actions in the event of accidental situations that might result in release to the environment. An active maintenance program will also be implemented.

Based on the described environmental assessment of manufactured Captrin, there will be no adverse environmental impacts. Thus, no mitigation procedures beyond those described are required for the material.

(4) Alternatives to the Proposed Action:

No alternative actions are proposed based on the environmental assessment presented above.

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(5) List of Preparers:

Those persons preparing the original assessment on May 26, 1994 were:

Dr. Arno Driedger
Director, Product Safety and Compliance
Stepan Company

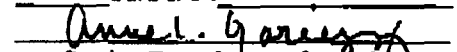
Dr. Dondeena Bradley
Business Development Manager
Food Ingredients Department
Stepan Company

Those persons preparing amendment to the original assessment are:

Annie L. Gariepy
Senior Regulatory Chemist
Stepan Company

(6) Certification:

The undersigned official certifies that the information presented is true, accurate and complete to the best of the knowledge of the firm or agency responsible for preparation of the environmental assessment.

(Date) 11/30/04
(Signature of Responsible Officer) 
(Title) Senior Regulatory Chemist

(7) Reference:

List complete citations for referenced materials.

November 30, 2004
417/b:051-GRAS